K011719

JUL - 2 2001

510(k) Summary of Safety and Effectiveness

[in accordance with SMDA of 1990, 21 CFR 807.92(c)]

Contact: Mr. Hartmut Loch, RAC
Director, Regulatory Affairs
PLUS ORTHOPEDICS
6055 Lusk Blvd.
San Diego, CA 92121-2700
Tel: 858.550.3800 x 2506

Establishment Registration #: 2086141

Classification:
Regulation #: 21 CFR 888.3040
Device Class: Class II
Classification Panel: 87 Orthopaedic Devices Panel
Product Code: HWC

Trade Name: PLUS Cancellous Bone Screws

Common Name: Bone Screws

Classification Name: Screw, Fixation, Bone

Description & Modification of Device: The PLUS cancellous bone screws are presently available, non-sterile, as part of complete instrument and implant sets for the following predicate devices manufactured by PLUS:

BOFOR® Revision Cup - K993874 – S/E/ 6/5/00
EPF®-PLUS Acetabular Cup - K994146 – S/E 12/11/00

These identical cancellous bone screws are now available, sterile, packaged individually in triple peel pouches (sterilized by Gamma irradiation). They are manufactured from Ti-6Al-4V ELI according to ASTM F136-98. They have a thread diameter of 6.5 mm and come in 10 lengths in 5 mm increments ranging from 15 mm to 60 mm. They have a standard 3.5 mm hexagonal screw head.

WARNING: These cancellous bone screws are not intended for spinal fixation.

Indications: The PLUS Cancellous Bone Screws are intended as a bone fixation device for a variety of surgical applications, such as fixation of press-fit acetabular cups in total hip arthroplasty or acetabular revisions, tibial components in total knee arthroplasty of knee revisions, and fixation of small and long bone fractures.

Contraindications: Contraindications include acute or chronic infections (local or systemic), serious lesions of muscles, nerves or blood vessels, bony defects or poor bone quality, any concurrent disease, which might interfere with the function of the cancellous bone screws, and the use for spinal fixation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Hartmut Loch, RAC
Director, Regulatory Affairs
PLUS Orthopedics
6055 Lusk Boulevard
San Diego, California 92121-2700

Re: K011719
Trade Name: PLUS Cancellous Bone Screws
Regulation Number: 888.3040
Regulatory Class: II
Product Code: HWC
Dated: June 1, 2001
Received: June 4, 2001

Dear Mr. Loch:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SPECIAL 510(K) DEVICE MODIFICATION
PLUS Cancellous Bone Screws
June 1, 2001

510(k) Number: K011719

Device Name(s):

PLUS Cancellous Bone Screws

Indications for Use:

The PLUS Cancellous Bone Screws are intended as a bone fixation device for a variety of surgical applications, such as fixation of press-fit acetabular cups in total hip arthroplasty or acetabular revisions, tibial components in total knee arthroplasty of knee revisions, and fixation of small and long bone fractures.

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PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

~~K011719~~ for cmw

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011719

Prescription Use X OR Over-The-Counter-Use ________
(Per 21 CFR 801.109) (Optional format 1-2-96)